

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1. (Presently amended): A bioadhesive, controlled, sustained release progressive hydration pharmaceutical composition in the form of a tablet, comprising:

an effective amount of an active ingredient that is a sex hormone,
a bioadhesive, water insoluble, water-swellable cross-linked polycarboxylic polymer, and
a water soluble polymer,

wherein said composition is formulated in a dry state to progressively hydrate and deliver, upon administration of said tablet to a mucosal surface of a mammal, said active ingredient to the bloodstream of said mammal.

Claim 2. (Previously presented): The composition of claim 1, wherein said active ingredient is present in about 50% by weight or less.

Claim 3. (Previously presented): The composition of claim 1, wherein said active ingredient is testosterone or progesterone.

Claim 4. (Previously presented): The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's vaginal cavity.

Claim 5. (Previously presented): The composition of claim 3, wherein said composition is formulated to deliver said active ingredient via the mammal's buccal cavity.

Claim 6. (Cancelled)

Claim 7. (Previously presented): A method of delivering to a mammal a sex hormone, comprising administering said sex hormone via a progressive hydration bioadhesive composition to a mucosal surface of the mammal, wherein said composition is formulated as a dry tablet that includes

- (a) said sex hormone,
- (b) a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer, and
- (c) a water-soluble polymer.

Claims 8-9 (Cancelled)

Claim 10. (Previously presented): A method of delivering testosterone to a mammal, comprising administering said testosterone via a bioadhesive, progressive hydration composition through a mucosal surface of the mammal, wherein the composition comprises:

a bioadhesive, water insoluble, water-swellable cross-linked polycarboxylic polymer,
a water soluble polymer, and
said testosterone,

and wherein said method provides a blood serum concentration ration of testosterone to 5α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

Claims 11-14. (Cancelled)

Claim 15. (Previously presented): The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via the mammal's nasal cavity.

Claim 16. (Previously presented): The composition of claim 1, wherein said composition is formulated to deliver said active ingredient via said mammal's rectal cavity.

Claims 17-18. (Cancelled)

Claim 19. (Previously presented): The method of claim 10, wherein said composition is administered through the mammal's buccal cavity.

Claim 20. (Previously presented): The method of claim 10, wherein said composition is formulated is administered through the mammal's vaginal cavity.

Claims 21-22. (Cancelled)

Claim 23. (Previously presented): A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,
a bioadhesive, water insoluble, water-swellable cross-linked polycarboxylic polymer,
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver a therapeutically effective amount of said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

Claim 24. (Previously presented): The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

Claim 25. (Previously presented): The pharmaceutical composition of claim 23, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

Claim 26. (Presently amended): A bioadhesive, controlled, sustained release progressive hydration composition for delivering testosterone to the bloodstream of a mammal, comprising:

a bioadhesive, water insoluble, water swellable cross-linked polycarboxylic polymer,

a water soluble polymer,
and testosterone,

wherein said composition is formulated to progressively hydrate upon application to a mucosal surface of said mammal and to deliver said testosterone through [[a]] said mucosal surface of the mammal, and to provide a blood serum concentration ratio of testosterone to 5 α -dihydrotestosterone (DHT) of about 10 to 1 or greater in the bloodstream of said mammal.

Claim 27. (Previously presented): The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's buccal cavity.

Claim 28. (Previously presented): The controlled, sustained release progressive hydration composition of claim 26, wherein said composition is formulated to deliver said testosterone via the mammal's vaginal cavity.

Claim 29. (Previously presented): The method of claim 7, wherein said mucosal surface is the mammal's vaginal cavity.

Claim 30. (Previously presented): The method of claim 7, wherein said mucosal surface is the mammal's buccal cavity.

Claim 31. (Previously presented): A bioadhesive, progressive hydration pharmaceutical composition comprising:

testosterone,
polycarbophil,
and a water soluble polymer,

wherein said composition is formulated to progressively hydrate and to deliver said testosterone to the bloodstream of a mammal through a mucosal surface of the mammal.

Claim 32. (Previously presented): The composition of claim 31, wherein the water soluble polymer is carbomer 974P.

Claim 33. (Previously presented): A method of administering testosterone to a mammal, comprising delivery of said testosterone via a progressive hydration bioadhesive composition to a mucosal surface of said mammal, wherein said composition includes

- (a) said testosterone,
- (b) polycarbophil, and
- (c) a water soluble polymer.

Claim 34. (Previously presented): The method of claim 33, wherein said water soluble polymer is carbomer 974P.